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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE-OPELOUSAS DIVISION

Charles Leblanc, et al. — Civil Action No. 04-0611

versus — Judge Tucker L. Melançon

Wyeth, Inc., et al — Magistrate Judge C. Michael Hill

MEMORANDUM RULING

Before the Court is a Motion for Summary Judgment filed by defendant Wyeth, Inc. (Wyeth) [Rec. Doc. 41] and an Opposition to Defendant Wyeth Inc.,'s Motion for Summary Judgment [Rec. Doc. 49] filed by plaintiffs. Wyeth has filed a Reply [Rec. Doc 58]. Plaintiffs have filed a Supplement to Plaintiffs' Opposition to Defendant Wyeth Inc.'s Motion for Summary Judgment [Rec. Doc. 65]. For the following reasons, the motion will be granted.

I. Background

This product liability case arises out of the ingestion by plaintiff Charles Leblanc (Leblanc or plaintiff) of the prescription drug amiodarone. Plaintiffs allege that Leblanc suffered injuries and pulmonary toxicity (or lung disease) as a result of this drug. On December 26, 2003, plaintiffs filed suit in the Sixteenth Judicial District Court, St. Mary Parish, Louisiana [Complaint, Rec. Doc. 1], naming as defendants, Wyeth and Prescription Management Services, Inc. (PMSI). Defendants removed the action to this Court under diversity jurisdiction, 28 U.S.C. §1332 [Notice of Removal, Rec. Doc. 2; Consent to Removal, Rec. Doc. 12]. In

their First Amended Complaint, plaintiffs added Teva Pharmaceuticals USA as a defendant [Rec. Doc. 24].

Plaintiffs do not dispute Wyeth's Statement of Uncontested Material Facts [Plaintiffs' Statement of Material Facts, Rec. Doc. 54 at para. 1][1]. Cordarone is a brand name prescription drug sold and distributed by Wyeth in tablet form for oral dosing [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 1]. The generic name of the drug sold and distributed by Wyeth as Cordarone is amiodarone [Id.]. Wyeth used to sell Cordarone in an intravenous ("IV") form, which was designated as National Drug Code ("NDC") 0008-0814 [Id.]. Wyeth's Cordarone tablet, its oral dosage form of amiodarone, bears NDC number 0008-4188 [Id. at para. 2]. Amiodarone is also marketed by other manufacturers using either the generic name of the drug or another brand name [Id.]. The amiodarone products marketed by companies other than Wyeth bear different NDC numbers [Id.].

On June 17, 2002, Dr. Vern Keller, a cardiovascular surgeon, performed quadruple coronary artery bypass surgery on Leblanc at the Medical Center of the Southwest [Id. at para. 3]. After the bypass surgery, Leblanc began to experience heart arrhythmias or irregular heart rhythms [Id. at para. 4]. Dr. Mohamad Khan, the treating cardiologist at the Medical Center of the Southwest, prescribed Cordarone to treat the arrhythmias [Id. at para. 5, Deposition of Dr. Khan, Wyeth's

[1]In their Statement of Material Facts, plaintiffs state, "they do oppose Wyeth's Motion for Summary Judgment, based not on this defendant's statement of undisputed facts, but rather on defendant's argument that based on these facts, this defendant is entitled to a judgment as a matter of law . . ." Plaintiffs' Statement of Material Facts, Rec. Doc. 54.

Exhibit B]. The prescribing information approved by the Food and Drug Administration provides the following about the risk of pulmonary toxicity:

> Cordarone is intended for use only in patients with the indicated life-threatening arrhythmias because its use is accompanied by substantial toxicity. Cordarone has several potentially fatal toxicities, the most important of which is pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) that has resulted in clinically manifest disease at rates as high as 10 to 17% in some series of patients with ventricular arrhythmias given doses around 400 mg/day, and as abnormal diffusion capacity without symptoms in a much higher percentage of patients. Pulmonary toxicity has been fatal about 10% of the time.

[Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 7]. When Dr. Khan prescribed to Leblanc, he had been adequately informed of the risks of Cordarone [Id. at 8, Deposition of Dr. Khan, Wyeth's Exhibit B, p. 28].

Leblanc received Amiodarone HCL (Cordarone) in oral tablet form through the pharmacy at the Medical Center of Southwest Louisiana during his stay from June 17, 2002 until his discharge on June 24, 2002 [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 9, Wyeth's Exhibit F]. It was and is the practice of the Medical Center of the Southwest Louisiana to purchase medication in the generic form, and plaintiffs admit they have no evidence to prove the Leblanc ingested brand name Cordarone manufactured by Wyeth from the Medical Center of the Southwest [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at paras. 10-11].

After his discharge, Leblanc filled a prescription for Cordarone written by Dr. Keller at Baldwin Drugs [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 12, Wyeth's H]. Records from Baldwin Drugs show that

Leblanc did not receive Wyeth's Cordarone when he filled his prescription [Id. at para. 13, Wyeth's Exhibit H]. Leblanc received generic amiodarone on June 24, 2002, bearing NDC number 00093-9133 and manufactured by Teva Pharmaceuticals USA [Id.].

Leblanc filled five prescriptions for Cordarone with Prescription Management Services, Inc., a mail order pharmacy, on July 18, 2002, August 7, 2002, August 30, 2002, October 2, 2002, and January 3, 2003 [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 14, Wyeth's Exhibit I]. PMSI filled Leblanc's Cordarone prescriptions with the generic amiodarone manufactured by Teva Pharmaceuticals USA and bearing NDC number 00093-9133 [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 15, Wyeth's Exhibit I, J].

In January, 2003 Leblanc sought treatment at the Iberia Medical Center and billing records show that he was charged for "Cordarone" in tablet form [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at paras. 16-17, Wyeth's Exhibit K]. According to the Director of Pharmacy at Iberia Medical Center, the only oral tablet form of amiodarone purchased by the pharmacy from January 1, 2002 through February, 2003 was a generic form called Pacerone, manufactured by Upsher Smith Laboratories, bearing NDC number 00245-0147 [Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 18, Wyeth's Exhibit L]. Iberia Medical Center pharmacy did not purchase Cordarone in tablet form from Wyeth at any time between January 1, 2002 and February 1, 2003

[Wyeth's Statement of Uncontested Material Facts, Rec. Doc. 76 at para. 19, Wyeth's Exhibit L].

In their Supplement to Plaintiffs' Opposition to Defendant Wyeth, Inc.'s Motion for Summary Judgment, plaintiffs submit Physician's Progress Notes and state that when their counsel reviewed Leblanc's medical records, including patient charts and doctors' progress notes prior to litigation, the hospital records indicated that Leblanc was prescribed brand name Cordarone on June 18, 2002. [Plaintiff's supplemental memorandum, Rec. Doc. 65 at Exhibit 1]. Plaintiffs state that recent discovery indicates that the hospital never ordered or dispensed brand name Cordarone [Plaintiffs' supplemental memorandum, Id. at para. 2]. Plaintiffs state that they have "not discovered any evidence that the hospital dispensing records are incorrect; accordingly, plaintiff does not dispute that Mr. Leblanc never ingested name brand Cordarone manufactured by Wyeth, Inc." [Id. at para. 2].

II. Motion For Summary Judgment Standard

Summary judgment is proper when the pleadings and evidence on file show that no genuine issue exists as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ. P. 56(c). The movant must inform the court of the basis of its motion and identify the portions of the record which reveal there are no genuine material fact issues. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "In adjudicating a motion for summary judgment, the court must view all facts in the light most favorable to the

non-movant." *Adams v. Travelers Indem. Co. of Conn.*, 2006 WL 2620585 at 3 (5th Cir. 2006). The function of the court, therefore, is to make the threshold inquiry of determining whether there is a need for a trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).[2] Once the movant makes this showing, the nonmovant must demonstrate that there is evidence in the record establishing that there is a genuine issue of material fact for trial. *Celotex* at 323-24. To carry this burden, the opponent must do more than simply show some metaphysical doubt as to the material facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). A dispute as to a material fact is "genuine" under Rule 56(c) only if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 251-52. The mere existence of a scintilla of evidence in support of the nonmovant's position is insufficient to preclude a grant of summary judgment. *Stewart v. Murphy*, 174 F.3d 530, 533 (5th Cir.1999). The opponent must present evidence sufficient to support a resolution of the factual issue in his favor. *Anderson*, 477 U.S. at 248-52. The court may properly enter summary judgment against a party if that party fails to establish the existence of an element essential to the case and as to which it will bear the burden of proof at trial. *Celotex*, 477 U.S. at 322-24. Summary judgment is also appropriate when the only issues to be decided in the case are issues of law, or when the non-moving party's claims are legally deficient. *Neff v. American Dairy Queen Corp.*, 58 F.3d 1063, 1065 (5th Cir.1995).

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[2]*See also Crawford-El v. Britton*, 523 U.S. 574, 600 (1998) ("Summary judgment serves as the ultimate screen to weed out truly insubstantial lawsuits prior to trial.").

III. Analysis

A. The Non-Louisiana Products Liability Act Claims

Plaintiffs allege that Wyeth negligently caused his injuries by: a) designing, manufacturing, marketing and distributing an unsafe drug; b) misrepresentation of the safety and/or dangers of Cordarone; c) conscious disregard for the general public's safety and health; d) failure to adequately test; (e) placing a defective or unreasonably dangerous drug into the stream of commerce; f) failure to properly warn; g) failure to exercise ordinary care in designing, manufacturing, marketing, selling, testing and/or distributing Cordarone; h) failure to provide sufficient instructions to plaintiff and/or dispensing physicians; and, i) any other negligence which may be proven at trial [Plaintiffs' Petition for Damages, Rec. Doc. 1 at X.] Plaintiffs also allege that Wyeth is liable to them under the theories of strict liability, strict products liability, negligence, redhibition, fraudulent misrepresentation and breach of implied and/or express warranties [Plaintiffs' Petition for Damages, Rec. Doc. 1 at XII].

Wyeth seeks summary dismissal of all claims not set forth in the Louisiana Products Liability Act, (LPLA), LSA-R.S.9:2800.51 *et seq.,* arguing that LPLA provides the exclusive theories of liability which can be asserted against product manufacturers under Louisiana law [Wyeth's memorandum, Rec. Doc. 41 at 8-10]. Plaintiffs do not respond to this argument in either their Opposition to Defendant Wyeth, Inc.'s Motion for Summary Judgment [Rec. Doc. 49] or their Supplement

to Plaintiffs' Opposition to Defendant Wyeth, Inc.,'s Motion for Summary Judgment [Rec. Doc. 65].

The Louisiana Products Liability Act, La.R.S. 9:2800.51, *et seq.*, provides the exclusive theories of liability for manufacturers for damage caused by their products. *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254 at 261-262 (5th Cir. 2002). In order to maintain a successful products liability action pursuant to the LPLA, a plaintiff must establish four elements: (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous;" and (4) that the claimant's damage arose from a reasonably anticipated use of the product. *Id.*, 283 F.3d at 260-61; *see* La.R.S. § 9:2800.54(A) A product is "unreasonably dangerous" under the LPLA if the product meets at least one of the following criteria:

> (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55;
> (2) The product is unreasonably dangerous in design as provided in R.S. 9:2800.56;
> (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided as provided in R.S. 9:2800.57; or
> (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.

Stahl, 283 F.3d at 261-2, *See* § 9:2800.54(B). "While the statutory ways of establishing that a product is unreasonably dangerous are predicated on principles of strict liability, negligence, or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent

theory of recovery against a manufacturer." *Jefferson v. Lead Industries Ass'n, Inc.*, 106 F.3d 1245 at 1251 (5th Cir. 1997)(incorporating district court opinion dismissing plaintiff's claims, 930 F. Supp. 241 (E.D.La. May 31, 1996) (J. Vance). The *Jefferson* Court also affirmed the district court's dismissal of the plaintiff's claims for fraud by misrepresentation *Id.* Accordingly, those claims brought by plaintiffs which are raised independent of the LPLA, including strict liability, negligence, fraudulent misrepresentation, and breach of express warranty will be dismissed.

Plaintiffs also allege that Wyeth is liable to them under the theory of redhibition. "Redhibition is the avoidance of a sale because of some vice or defect in the thing sold." *Capitol City Leasing Corp. v. Hill*, 404 So.2d 935 at 939 (La., 1981). As to claims for redhibition raised in connection with products liability claims, the *Jefferson* court noted, ". . . breach of implied warranty or redhibition is not available as a theory of recovery for personal injury, although a redhibition action is still viable against the manufacturer to recover pecuniary loss." *Jefferson,* 106 F.3d 1245 at 1251. Accordingly, as to plaintiffs' allegations that Wyeth is liable to them under the theory of redhibition, to the extent that plaintiffs assert claims for redhibition for personal injuries, these claims are not available under the LPLA and will be dismissed. Further, to the extent that plaintiffs allege claims for redhibition for economic losses, these claims will be dismissed as plaintiffs have not disputed that Leblanc did not ingest a Wyeth product.

B. The LPLA Claims

Wyeth argues that Leblanc never ingested its product so that summary judgment must be granted in its favor as plaintiffs are required under the LPLA to prove that it was the manufacturer or seller of the drug ingested by Leblanc [Wyeth's memorandum in support of motion for summary judgment, Rec. Doc. 41 at 10-11, Wyeth's reply to plaintiffs' opposition, Rec. Doc. 58 at 1-2]. Wyeth argues that, since plaintiffs responded to Wyeth's request for documents supporting their claims that Leblanc ingested the Cordarone brand name of amiodarone, bearing National Drug Code number 0008-4188 with *only* an invoice from Iberia Medical Center, then plaintiffs have conceded that they have no evidence that Leblanc ingested Cordarone from another source [Wyeth's motion for summary judgment, Rec. Doc. 41 at Wyeth's Exhibit E]. Wyeth submits the affidavit of the Iberia Medical Ctr.'s Director of Pharmacy that the pharmacy purchased only the oral form of amiodarone between January 1, 2002 and February 1, 2003, arguing that Leblanc could and did not receive Wyeth's product at Iberia Medical Ctr [Wyeth's Exhibit L].

Wyeth further submits records from the Medical Center of the Southwest [Wyeth's Exhibit F] showing Leblanc received "amiodarone HCL (Cordarone)" and the affidavit of its Director of Pharmacy that, during the year 2002, only the generic form of products such as amiodarone were purchased if available [Wyeth's Exhibit G]. Wyeth states that the generic amiodarone has been available since 1998 [Wyeth's memorandum, Rec. Doc. 41 at 5]. Wyeth also argues that

plaintiffs have conceded that Leblanc did not receive Cordarone at the Medical Center of the Southwest by not producing such evidence to them in discovery [Id.].

Wyeth submits records from Baldwin Drugs and plaintiffs' discovery responses to evidence that these drug purchases were of the generic amiodarone [Wyeth's Exhibits E, H]. Additionally, Wyeth submits discovery responses from PMSI to show that it filled Leblanc's prescription with the generic amiodarone [Wyeth's Exhibits I, J].

Plaintiffs state that they named Wyeth as a defendant because their counsel relied on Leblanc's medical records, including patient charts and doctors' progress notes, which indicated that Leblanc was prescribed brand name Cordarone on June 18, 2002. [Plaintiff's supplemental memorandum, Rec. Doc. 65 at Exhibit 1]. Although this document relates to Leblanc's admission at the Medical Center of the Southwest rather than Iberia Medical Ctr., as discussed by defendant and referenced in plaintiffs' discovery responses, plaintiffs state that during the discovery process all sources of amiodarone hydrochloride that Leblanc ingested were identified and that plaintiffs cannot establish that brand name Cordorone was ever dispensed or ingested by plaintiff [plaintiffs' supplemental memorandum in opposition to Wyeth's motion for summary judgment, Rec. Doc. 65]. Plaintiffs state that hospital dispensing records indicate that only Cordarone bioequivalent drugs were dispensed to Leblanc during the time frame at issue, that they have not discovered evidence that these records are incorrect and do not dispute that Leblanc never ingested name brand Cordorone manufactured by Wyeth [Id.].

Plaintiffs initially argued in their opposition that Wyeth should be held liable for any damage caused by inadequate warnings associated with generic versions of Cordorone because, as the manufacturer of the "reference listed" drug, Wyeth is responsible for establishing the safety and efficacy of Cordorone and, by extension its bioequivalent drug amiodarone [plaintiffs' opposition to Wyeth's motion for summary judgment, Rec. Doc. 49 at 3]. However, plaintiffs appear to have conceded this argument as they state in their supplemental memorandum that, "LSA R.S. 9:2800.5 requires plaintiff to prove harm was caused by a product manufactured by Wyeth [Id. at 2]." In a case in which the plaintiff admitted that she had ingested only the generic version of the drug at issue but argued that the brand-name producer had a duty to warn all users of the drug's dangers, including the generic competitor's products, the plaintiff based her argument on the premise that generic manufacturers "have taken the position" in past litigation that they are prohibited by the Food and Drug Administration from changing the warnings created by the brand-name manufacturer. The plaintiffs argued that, if that is so, there would be no liability against the generic manufacturer for failure to warn, and, if liability is not imposed on the brand-name manufacturer, an injured plaintiff would have no recourse. Without deciding the issue whether generic manufacturers have the ability to change labeling, the Court rejected plaintiff's argument, holding "[t]he law is clear that Louisiana imposes on a manufacturer no duty to warn of the dangers of another company's product," *Tarver v. Wyeth, Inc.*, 2005 WL 4052382 at 2 (W.D.La. June 7, 2005), *relying on Fricke v. Owens-*

Corning Fiberglass Corp., 618 So.2d 473 (La.App.1993); *Roberts v. Bioplastics,* 93-2967, 2000 WL 34487072 (E.D.La., 2000). As plaintiffs have not raised a genuine issue of material fact that Wyeth was the manufacturer of the drug ingested by Leblanc, an essential element under the LPLA, the Court will dismiss these claims.

Wyeth also argues that plaintiffs' claims are barred under the learned intermediary doctrine as Leblanc's prescribing physicians were adequately warned [Wyeth's memorandum in support of motion for summary judgment, Rec. Doc. 41 at 12]. Plaintiffs argue in their opposition that Wyeth's warning, provided as a product insert and published in the Physician's Desk Reference, was inadequate [plaintiffs' opposition, Rec. Doc. 49]. Plaintiffs contend that due to the uniquely toxic nature of amiodarone, Wyeth should have the duty to warn the plaintiff himself, not only his physician [Id. at 5]. Plaintiffs argue that, if the Court applies the learned intermediary doctrine, Wyeth's reliance on Drs. Keller and Kowalski's testimony is misplaced since "these two doctors have a personal stake in the outcome of the litigation as there is also a medical malpractice claim lodged against both of them [Id. at 5]. Plaintiffs also argue that defendant has been required to make changes to its warnings, as the drug proves to be more dangerous and more commonly prescribed for off label use but these heightened warnings do not appear to deter physicians [Id. at 6]. Therefore, plaintiffs assert that the drug should be taken off the market or placed in a limited access program [Id.]. As plaintiffs have not produced summary judgment evidence that Leblanc took a

Wyeth amiodarone product, and, in fact, do not dispute that Leblanc never ingested name brand Cordorone manufactured by Wyeth, Inc., it is unnecessary to reach the issue whether or not the Cordarone labeling was adequate.

Conclusion

For all of the foregoing reasons, the Court finds Wyeth, Inc.'s motion to have merit and, therefore, plaintiffs' claims against Wyeth, Inc. will be dismissed.

JLM